IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

FEDERAL TRADE COMMISSION, et al., **Plaintiffs,** **v.** **VYERA PHARMACEUTICALS, LLC, et al.,** **Defendants.**	**Case No.: 1:20-cv-00706-DLC**

Plaintiffs' Memorandum of Law in Opposition to Defendants Vyera Pharmaceuticals, LLC and Phoenixus AG's Motion to Dismiss

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The complaint in this government enforcement action tells a straightforward story of anticompetitive conduct. In 2015, Defendant Vyera Pharmaceuticals, LLC[1] purchased Daraprim—an old, off-patent, essential drug with no generic alternative—and immediately raised the price by 4,000%. To protect the resulting profits from competition by lower-cost generic versions, Vyera created an elaborate web of restrictive agreements: It entered resale-restriction agreements with distributors and purchasers that prevent potential generic competitors from acquiring the Daraprim they need to conduct FDA-mandated testing. It signed exclusivity agreements with suppliers that prevent generic companies from purchasing a key ingredient for their products. And it inked data-blocking agreements with distributors that prevent generic companies from accessing the data they need to assess the market opportunity for Daraprim.

Vyera's anticompetitive scheme is unlawful. The purpose and effect of these restrictive agreements—most of which remain in place today—is to impede and delay lower-cost generic competition to Daraprim. It is egregious. It forces vulnerable American consumers to pay a steep price for a life-saving product that had been affordable for decades. And it is no accident. Defendant Martin Shkreli, with help from Defendant Kevin Mulleady, founded Vyera for the specific purpose of purchasing old but essential drugs like Daraprim, imposing an enormous price increase, and using restrictive agreements to prevent competition.

In its motion to dismiss, Vyera first argues that the FTC's claims are barred because it lacks statutory authority to sue in federal court over "conduct solely in the past." But Vyera's factual premise is simply wrong: Plaintiffs allege *ongoing* misconduct. And even if that were not the case, Vyera's legal argument rests entirely on a single out-of-circuit decision, *FTC v. Shire ViroPharma*, that is inconsistent with Second Circuit precedent and has been repeatedly

[1] Unless otherwise specified, this brief refers to Vyera and its co-Defendant and parent company, Phoenixus AG, collectively as "Vyera" when discussing their joint conduct relating to Daraprim.

distinguished by subsequent courts due to its unusual facts. Vyera's further argument that Pennsylvania and New York lack statutory authority for some of their claims similarly fails.

Vyera next contends that each aspect of its scheme to maintain its lucrative Daraprim monopoly (within the meaning of Sherman Act Section 2) is immune from challenge. All of these arguments miss the mark.

First, Vyera asserts that it is free to enter resale-restriction agreements with distributors and purchasers because it has an absolute right to refuse to deal with competitors. But the Supreme Court has long made clear that no such right applies when a defendant enters restrictive agreements that dictate how *others* sell its product.

Second, Vyera contends that its exclusivity agreements with the two most viable suppliers of a critical Daraprim ingredient cannot violate the antitrust laws because the complaint does not categorically allege that there was no other possible source of that ingredient. But Defendants both ignore the law—there is no requirement that a defendant *completely* foreclose its competitors—and ignore the specific allegations that Vyera's exclusivity agreements impeded and delayed multiple generic companies by a year or more.

Third, Vyera argues that Plaintiffs' data-blocking claims are facially implausible—despite specific allegations that they worked as intended and deterred a major generic pharmaceutical company from developing generic Daraprim.

Vyera further argues that all of Plaintiffs' agreement-in-restraint-of-trade claims (which rest on Sherman Act Section 1 principles) must be dismissed because Vyera's written contracts—in which distributors, purchasers, and API suppliers agree not to sell to generic companies—do not count as antitrust "agreements" unless Plaintiffs also allege that the counterparties shared Vyera's anticompetitive motives. But such evidence is only relevant to

exclude the possibility that the parties were acting independently in cases *without an express agreement*. As the Supreme Court and Second Circuit have repeatedly found, a written agreement to engage in the challenged conduct obviates the need for additional circumstantial evidence of agreement. For these reasons, Vyera's motion to dismiss should be denied.

BACKGROUND

Generic drugs and the FDA approval process

Generic versions of branded drugs, which typically enter the market at a steep discount to the brand price, play a critical role in lowering prescription drug prices in the United States and provide enormous benefit to consumers. Amended Complaint for Injunctive and Other Equitable Relief, Apr. 14, 2020, ECF No. 87 ("Am. Compl.") ¶¶ 65-68. Generic entry also typically has a dramatic and immediate impact on the sales of the corresponding brand drug. Within six months of generic entry, a brand drug can lose up to 80% of its unit and dollar sales. *Id*. ¶ 68.

To facilitate generic drug competition, Congress created a streamlined path for FDA approval. *Id.* ¶¶ 54, 56. A generic applicant can submit an Abbreviated New Drug Application ("ANDA") without the same showing of safety and efficacy that the brand manufacturer had to make to gain FDA approval. Instead, the generic applicant need only show that its generic drug is therapeutically equivalent—or "bioequivalent"—to the brand version, meaning that it has the same active ingredient with the same rate and extent of absorption as the brand drug. *Id.* ¶¶ 56-57.

To conduct the required bioequivalence studies, the generic applicant must obtain substantial quantities of the brand product. *Id.* ¶¶ 58-60. This is usually easy; it can buy the brand product through normal distribution channels, such as from pharmacies or drug wholesalers. *Id.* ¶¶ 61, 94. If a generic company is unable to procure sufficient quantities, however, it cannot complete the required testing and thus cannot obtain FDA approval.

A generic applicant must also secure a reliable supply of the drug's active pharmaceutical ingredient ("API"). *Id.* ¶ 62. The FDA must separately approve the API product, the manufacturing process used to make it, and the manufacturer's quality controls, facility, and practices. *Id.* If a generic applicant cannot find an API supplier with an existing process that meets FDA standards, it will typically work with a manufacturer to develop and validate a new manufacturing process, which can take a year or more and cost [redacted]. *Id*. ¶¶ 63, 174-75.

Vyera acquires Daraprim

Vyera was founded in 2014 by Defendant Martin Shkreli with assistance from Defendant Kevin Mulleady. Am. Compl. ¶¶ 35-36, 50. Shkreli founded Vyera with the explicit purpose of buying a sole-source, off-patent drug, executing a massive price hike, and then using an anticompetitive strategy to block generic competition. *Id*. ¶¶ 36, 86, 292-94. Ultimately, Defendants settled on Daraprim as the right candidate for this scheme.

Prior to February 2020,[2] Daraprim had been the only FDA-approved drug containing the active ingredient pyrimethamine, which is the gold-standard treatment for toxoplasmosis. *Id*. ¶¶ 73, 78. Toxoplasmosis is a parasitic infection that is potentially fatal in immunocompromised patients. *Id*. ¶¶ 69-71. It is relatively rare, with less than 7,000 cases per year in the United States. *Id.* ¶ 72.

Daraprim was approved by the FDA in 1953. *Id.* ¶ 75. It had been sold as an affordable, life-saving treatment for more than 60 years. By 2010, it cost about $1 per tablet. *Id.* ¶¶ 79-80. By 2015, after several ownership changes, the price was $17.50 per tablet. *Id.* ¶¶ 82-85.

[2] On February 28, 2020, the FDA approved a generic version of Daraprim. Am. Compl. ¶ 78.

In August 2015, Vyera acquired Daraprim and immediately raised the price from $17.50 to $750 per tablet—an increase of more than 4,000%. *Id.* ¶ 89. This massive price increase delivered immediate benefits to Vyera, increasing Daraprim's annual revenues from [redacted] to over [redacted]. *Id.* ¶¶ 2, 87. But Vyera knew this revenue boon could be temporary: Daraprim had long ago lost any patent protection or regulatory exclusivity, and the massive price increase would attract competition from lower-priced generic versions. *Id*. ¶¶ 3, 75, 93.

Vyera's anticompetitive scheme to impede and delay generic Daraprim competition

To impede generic competition and protect its Daraprim monopoly, Vyera entered into an elaborate web of restrictive agreements with market participants at every level of its distribution and supply chains to deny potential generic competitors access to key inputs.

Resale-restriction agreements with distributors and purchasers. Before 2015, Daraprim was distributed openly for more than 60 years without any restrictions; generic companies could easily obtain it from a local pharmacy. Am. Compl. ¶ 94. But Defendants understood that a restricted distribution system "can be a way to lower competition" because it "prevent[s] generics from potentially getting [the] referenced product" needed for bioequivalence testing. *Id.* ¶ 95. Upon acquiring Daraprim, Vyera entered agreements with Daraprim distributors and purchasers to prevent them from selling the product to generic drug manufacturers without Vyera's approval.

Vyera's agreements with distributors allow them to sell only to certain authorized purchasers unless Vyera separately approves the sale. *Id.* ¶¶ 100-112. None of these agreements authorizes sales to generic companies or suppliers working on their behalf. *Id*. ¶¶ 100, 103, 106, 108, 110, 112-13. And Vyera does not approve sales to generic companies. *Id.* ¶¶ 101, 113. Vyera's agreements with downstream purchasers such as hospitals and pharmacies contain

similar restrictions. *Id.* ¶¶ 118-22. This web of distribution restrictions was "an integral part of the company's desire to block a generic entrant for at least three years." *Id.* ¶ 95.

Vyera's agreements with distributors and purchasers also include quantity limits. *Id*. ¶¶ 123-25. Defendants are aware that any potential generic competitor will need at least 5 to 10 bottles of Daraprim to conduct bioequivalence testing. *Id.* ¶ 124. Thus, even for authorized customers, Vyera's agreements limit the amount of Daraprim a buyer can purchase. *Id.* ¶ 125. The quantity limits are intended to reduce the risk "that a generic company could access multiple bottles of [Daraprim], perhaps obtained through a hospital reselling it or distributing product to surrounding retail pharmacies." *Id.* As recently as August 2019, Shkreli and Mulleady discussed further limiting all Daraprim sales to one bottle at a time to prevent a generic company from "get[ting its] hands on anything." *Id.* ¶ 129. Vyera's agreements restricting resale and limiting quantity remain in effect today. *Id.* ¶¶ 102-113, 118-22, 126-28, 135, 320.

Vyera also aggressively monitors sales to ensure compliance with its resale restrictions and quantity limits. Upon becoming CEO of Vyera in 2017, Mulleady ordered a "full out audit of daraprim" so he could "know where every bottle of daraprim we sold went to." *Id*. ¶ 130. From this aggressive monitoring, Vyera learned that a company called Centrastate Specialty Script had purchased a larger-than-normal quantity of five bottles. *Id.* ¶ 131. Fearing that Centrastate might re-sell the product to a generic company, Mulleady bought back all five bottles at [redacted] the cost and Vyera barred Centrastate from future purchases. *Id.* ¶¶ 131-33.

Exclusive API agreements. Vyera also knew that any potential generic competitor would need a reliable source of pyrimethamine API. Am. Compl. ¶ 145. To deprive generic competitors of access to this critical ingredient, Defendants entered into exclusivity agreements with the two most viable manufacturers of pyrimethamine API. *Id.* ¶ 144.

First, in January 2017, Phoenixus signed a [redacted] with Fukuzyu with [redacted]. *Id*. ¶ 153. Fukuzyu had long sold pyrimethamine API for use in Daraprim. *Id.* ¶ 151. Vyera knew that the FDA had approved Fukuzyu's API and manufacturing process and thus any potential competitor could use Fukuzyu's API immediately. *Id.* ¶ 151. During negotiations, Vyera informed Fukuzyu that exclusivity was "the most critical issue[]" and that "[i]f generic products are put on the U.S. market, [Vyera] will face a serious problem." *Id.* ¶ 155.

Under the exclusivity agreement, Fukuzyu commits that it will not sell pyrimethamine API to anyone but Vyera for human use in the United States. *Id.* ¶ 154. The exclusivity agreement does not ensure Vyera any minimum supply of API or reflect any investment Vyera made. *Id.* ¶ 157. Instead, its purpose is to ensure that Fukuzyu "will not sell to generic manufacturers." *Id.* ¶ 152. The Fukuzyu API exclusivity agreement remains in effect today. *Id.* ¶ 158.

After locking up Fukuzyu, Defendants moved to sideline the next most viable API manufacturer, RL Fine Chem Pvt. Ltd. *Id.* ¶ 159. Vyera became aware that RL Fine was working to supply pyrimethamine API to two potential generic competitors. *Id.* ¶ 160. RL Fine had never supplied this product to the U.S. market. But its pyrimethamine API manufacturing process had been approved for use in the European Union, indicating that its facilities, and manufacturing practices were likely sufficient to obtain FDA approval. *Id.* Even though Defendants had no need for a second source of API, Shkreli directed Mulleady and another executive to poach RL Fine from the generic companies and sign it to an exclusivity agreement. *Id.* ¶¶ 161-63, 168.

In December 2017, Vyera executed its agreement with RL Fine. In it, RL Fine designated Vyera as its exclusive distributor of pyrimethamine API. Vyera had no API distribution

capabilities and no intention to become an API distributor, but this designation gave it the power to block any sale of pyrimethamine API to a potential generic competitor. *Id.* ¶ 165. After signing the agreement, Vyera directed RL Fine to stop supplying pyrimethamine API to the two generic companies with which it had been working. *Id.* ¶ 165.

In exchange for this exclusivity, Vyera agreed to pay RL Fine [redacted] (ostensibly in part for a separate agreement that neither party pursued) and [redacted], amounting to [redacted] to [redacted] per month. *Id.* ¶¶ 164-66. Vyera agreed to make these payments irrespective of whether it took API from RL Fine (which it never did) or whether RL Fine's API was approved for use in Daraprim (which it never was). *Id.* ¶ 166. Years after signing the agreement, Vyera's chief scientific officer in charge of Daraprim manufacturing was not even aware the company had a contract with RL Fine. *Id.* ¶ 171. Yet, Vyera paid RL Fine approximately [redacted] under the agreement. *Id.* ¶ 166.

On October 25, 2019—three months before this case was filed—Vyera paid RL Fine another [redacted] to terminate the agreement. By that time, the FTC had solicited extensive testimony and documentary evidence about the RL Fine deal. *Id.* ¶ 172.

Fukuzyu and RL Fine were the only suppliers with an existing pyrimethamine API manufacturing process that was likely to meet FDA standards. *Id.* ¶¶ 173-75.

Data-blocking agreements. A generic company typically analyzes the brand product's sales to assess the potential market opportunity before investing in generic product development. Am. Compl. ¶ 177. Generic companies acquire the data for this analysis from companies like IQVIA. *Id.* ¶ 178. IQVIA and other similar data aggregators purchase sales data from drug distributors and pharmacies, aggregate it, and sell compiled datasets to industry participants. *Id.*

Vyera correctly feared that increased sales from its Daraprim price hike would attract generic competitors. *Id.* ¶ 182. To prevent this, Vyera entered "data-blocking" agreements with two major distributors under which the distributors agreed (in exchange for a fee) to stop selling their Daraprim sales data to IQVIA or similar companies. *Id.* ¶¶ 181-85. Vyera's goal was "to prevent external visibility into [Vyera's] corporate performance" *Id.* ¶ 188. Without sales from these major distributors, IQVIA's Daraprim data is "extremely incomplete and not very useful." *Id.* ¶ 186. Because Vyera is a privately-held company that does not publicly report Daraprim sales, generic companies have no other way to obtain accurate market data. *Id*. ¶ 180. At least one major generic company abandoned efforts to develop generic Daraprim because it could not estimate the market opportunity due to Defendants' data-blocking agreements. *Id.* ¶¶ 262-66.

Vyera's anticompetitive scheme impeded and delayed generic competition

Vyera's combination of resale-restriction agreements, API exclusivity agreements, and data-blocking agreements impeded and delayed multiple potential generic competitors.

[redacted] first began developing generic Daraprim in 2013, before Vyera acquired the drug. Am. Compl. ¶ 194. That year, [redacted] bought nine bottles of Daraprim from a local pharmacy with no difficulty. *Id.* ¶¶ 196-97. In 2014, [redacted] submitted its ANDA to the FDA. *Id.* ¶¶ 198-99. [redacted], however, was abruptly forced to locate a new API supplier when its original supplier, Ipca, was banned from importing into the United States. *Id.* ¶ 200.

In 2016, [redacted] reached a supply agreement with Fukuzyu. *Id.* ¶ 201. But shortly thereafter, Fukuzyu backed out of the deal because it had signed the exclusivity agreement with Vyera. *Id.* ¶ 202. [redacted] then entered a supply agreement with [redacted] and purchased a limited quantity of pyrimethamine API. *Id.* ¶¶ 204, 220. Switching API suppliers, however, required [redacted] to redo its bioequivalence testing. *Id.* ¶ 206. To do so, [redacted] had to obtain new samples of branded Daraprim. *Id.*

By this time, Vyera had implemented its resale restrictions, and [redacted] could not buy Daraprim from distributors or pharmacies. [redacted] tried for more than a year to purchase sufficient samples—both directly and through intermediaries—and ultimately was only able to obtain [redacted] of the six [redacted] it needed. *Id.* ¶¶ 207-13. [redacted] *Id.* ¶ 214. [redacted] *Id.* [redacted] *Id.* ¶ 215.

[redacted] began developing generic Daraprim in [redacted]. *Id.* ¶ 223. Like [redacted], it easily purchased six bottles of Daraprim from a local pharmacy. *Id.* ¶ 225. [redacted] turned to [redacted] as an API supplier after its initial supplier was banned from importing into the U.S. *Id.* ¶¶ 227-30. In [redacted], [redacted] agreed to supply [redacted] with API and to cooperate on the technical aspects of FDA approval. *Id.* ¶ 230. Shortly thereafter, [redacted] broke this agreement after signing the exclusivity agreement with Vyera. *Id.* ¶¶ 232-33. This forced [redacted] to work with a new supplier, [redacted], which did not have a pyrimethamine API manufacturing process. [redacted] spent [redacted] transferring [redacted] manufacturing process to [redacted]. *Id.* ¶¶ 235-37. [redacted] *Id.* ¶ 237.

[redacted] began developing generic Daraprim in early 2016 after learning of Vyera's dramatic price increase. *Id.* ¶ 241. It reached out to Fukuzyu multiple times, but due to the Vyera exclusivity agreement, Fukuzyu would not supply [redacted]. *Id.* ¶¶ 242, 244-46. Unable to partner with Fukuzyu, [redacted] worked with [redacted], which did not

have a pyrimethamine API manufacturing process. *Id.* ¶ 243. It took three years for [redacted] to develop a suitable process. *Id.* ¶ 247.

[redacted] was also impeded by its inability to obtain Daraprim samples. [redacted] began trying to buy Daraprim in late 2016. *Id.* ¶ 249. Like [redacted], it tried to purchase Daraprim for more than a year, both directly and through intermediaries, [redacted]. *Id.* ¶¶ 249-54, 258. [redacted] *Id.* ¶¶ 259-60.

Filing of the complaint and subsequent events

On January 27, 2020, the FTC and State of New York jointly filed a sealed complaint against Defendants in this Court. This complaint outlines Defendants' conduct and alleges that Defendants' "unlawful scheme to maintain a monopoly on Daraprim continues to this day." Plaintiffs' Complaint for Injunctive and Other Equitable Relief, Jan. 27, 2020, ECF No. 2 ("Compl.") ¶ 1. When the complaint was filed, Defendants' current contracts with distributors and purchasers still barred the resale of Daraprim to generic companies. *Id*. ¶¶ 94-107, 113-16, 121-22, 128. Vyera's API exclusivity agreement with Fukuzyu was still in effect. *Id*. ¶ 152. No generic company had received FDA approval or entered the market. *Id*. ¶¶ 271-73, 282. And the complaint alleges that Vyera continued to possess monopoly power with respect to Daraprim. *Id*. ¶ 287. The prayer for relief requests "[t]hat Defendants are permanently enjoined from continuing their course of conduct." *Id.* Prayer for Relief 7.

On February 28, 2020, the FDA approved Cerovene's generic Daraprim. Am. Compl. ¶ 216. Two weeks later, a Phoenixus subsidiary announced that it would launch an "authorized

generic" version of Daraprim. *Id.* ¶ 217.[3] On March 20, 2020, seven years after it started development, Cerovene (with the help of its commercial partner) launched generic pyrimethamine. *Id.* ¶ 218.

[redacted] Vyera poached that supplier. *Id.* ¶ 220. [redacted] Vyera's still-in-place resale restriction agreements [redacted]. *Id*.

On April 14, 2020, the FTC and New York filed an amended complaint adding six more State Plaintiffs—California, Illinois, North Carolina, Ohio, Pennsylvania, and Virginia. The amended complaint alleges that Defendants' "unlawful scheme to maintain a monopoly on Daraprim continues to this day" and that Vyera's restrictive agreements remain in place. Am. Compl. ¶¶ 1, 99-113, 118-22, 134-36, 158. It includes updated factual allegations to reflect the intervening FDA approval and entry of Cerovene's generic product. *Id.* ¶¶ 216-18. But it makes "virtually no change to the substantive allegations from the initial complaint." Mem. of Law in Support of Mot. to Dismiss by Defs. Vyera Pharmaceuticals, LLC and Phoenixus AG, ECF No. 118 ("Mem.") 26 n.10. The amended complaint requests that Defendants be "permanently enjoined from continuing their course of conduct." Am. Compl. Prayer for Relief 14.

[3] An authorized generic product is chemically identical to the brand drug but sold under a generic label. A brand company often launches an authorized generic version of its product when it expects generic entry in order to retain some revenues it would otherwise lose to a generic competitor. Am. Compl. ¶ 217.

ARGUMENT

Vyera contends that the FTC lacks authority to bring this lawsuit in federal court, that New York and Pennsylvania lack authority to bring certain claims, and that Plaintiffs fail to state cognizable antitrust claims under federal and state law. When a party moves to dismiss under Rule 12(b)(6), the court must "constru[e] the complaint liberally, accepting all factual allegations as true, and drawing all reasonable inferences in the plaintiff's favor." *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220, 230 (2d Cir. 2016). Plaintiffs' factual allegations need only "be enough to raise a right to relief above the speculative level" to state a claim that is "plausible on its face." *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 555-56, 570 (2007). Under these well-settled standards, Plaintiffs have properly invoked their statutory authority to bring this lawsuit and have stated claims that Vyera's use of an ongoing, multi-faceted scheme to maintain its monopoly on Daraprim through numerous anticompetitive agreements violates federal and state antitrust laws.

I. The FTC's claims are properly in federal court

Section 13(b) of the FTC Act empowers the FTC to file suit in federal court when it has reason to believe a defendant "is violating, or is about to violate" the antitrust laws. 15 U.S.C. § 53(b). Citing the Third Circuit's decision in *FTC v. Shire ViroPharma*, 917 F.3d 147 (3d Cir. 2019), Vyera argues that the FTC lacks authority to sue in federal court because this case challenges only "past conduct" and does not allege an "imminent" future violation. Mem. 14-20. But the factual premise of this argument is wrong. Unlike in *Shire*, where the alleged violation undisputedly had ended five years before the FTC filed suit, here the FTC challenges Vyera's ongoing anticompetitive conduct. Moreover, even if Vyera's illegal conduct had ended, the FTC's suit is still authorized by Section 13(b) because the FTC had sufficient reason to believe Vyera's unlawful conduct is likely to recur. Vyera's contention that the FTC must plead an

"imminent" recurrent violation misreads *Shire* and is inconsistent with Second Circuit precedent interpreting virtually identical statutory language in analogous provisions of the securities laws.

A. Section 13(b) authorizes the FTC to sue whenever it has "reason to believe" a defendant is violating or is about to violate the law

The FTC enforces Section 5 of the FTC Act, which prohibits "[u]nfair methods of competition," 15 U.S.C. § 45(a), and encompasses violations of the Sherman Act.[4] Before 1973, the FTC could enforce the FTC Act against antitrust violations only through internal administrative adjudicative proceedings. In 1973, Congress enacted Section 13(b) to provide additional enforcement mechanisms. It currently reads, in relevant part:

> Whenever the Commission has reason to believe—
>
> (1) that any person, partnership, or corporation is violating, or is about to violate, any provision of law enforced by the Federal Trade Commission, and
>
> (2) that the enjoining thereof pending the issuance of a complaint by the Commission and until such complaint is dismissed by the Commission or set aside by the court on review, or until the order of the Commission made thereon has become final, would be in the interest of the public—
>
> the Commission by any of its attorneys designated by it for such purpose may bring suit in a district court of the United States to enjoin any such act or practice. Upon a proper showing that, weighing the equities and considering the Commission's likelihood of ultimate success, such action would be in the public interest, and after notice to the defendant, a temporary restraining order or preliminary injunction may be granted without bond: *Provided, however*, That if a complaint is not filed within such period (not exceeding 20 days) as may be specified by the court after issuance of the temporary restraining order or preliminary injunction, the order or injunction shall be dissolved by the court and be of no further force and effect: ***Provided further*, That in proper cases the Commission may seek, and after proper proof, the court may issue, a permanent injunction**.

15 U.S.C. § 53(b) (emphasis added).

[4] *FTC v. Ind. Fed'n of Dentists*, 476 U.S. 447, 454 (1986).

Section 13(b) contains two distinct grants of authority. The first part of the statute authorizes the FTC to seek a preliminary injunction or temporary restraining order in federal court to stop ongoing or threatened conduct while the FTC conducts an internal administrative trial. The second grant of authority, the "permanent injunction proviso," (bolded above) allows the Commission to litigate its entire case in federal court, rather than under the Commission's administrative process, when the Commission finds it to be a more effective way to protect consumers. *See United States v. JS & A Grp., Inc.*, 716 F.2d 451, 456 (7th Cir. 1983); *FTC v. H.N. Singer, Inc.*, 668 F.2d 1107, 1110-11 (9th Cir. 1982). The FTC brought this case, like the majority of its Section 13(b) cases, under the second authorization.[5]

By its terms, Section 13(b) does not condition the FTC's ability to sue in federal court on whether a defendant *in fact* "is violating" or "is about to violate" the law. Rather, the statute permits the FTC bring suit when it has "*reason to believe*" they are. 15 U.S.C. § 53(b) (emphasis added). Some courts have held that FTC "reason to believe" determinations are unreviewable.[6] Others have concluded a limited judicial review is permitted to confirm that the Commission made a "reason to believe" determination.[7] Given Rule 12(b)(6)'s lenient plausibility standard, Section 13(b) thus imposes—at most—a minimal pleading burden: The FTC need only allege "at

[5] The Commission frequently uses the first authority to enjoin proposed mergers that may lessen competition while the agency conducts an administrative adjudication.

[6] *See FTC v. Nat'l Urological Grp., Inc*., Civil Action No. 1:04-cv-3294-CAP, 2006 WL 8431977, at *5 (N.D. Ga. Jan. 9, 2006) (holding judicial review "impossible" because Section 13(b) provides "no meaningful standard by which to measure the lawfulness of the FTC's actions"); *Boise Cascade Corp. v. FTC*, 498 F. Supp. 772, 779 (D. Del. 1980) (judicial review of FTC reason to believe determination under Section 5 of the FTC Act would require the court to "probe [the Commissioners] mental processes, a practice condemned by the Supreme Court").

[7] *See AMREP Corp. v. FTC*, 768 F.2d 1171, 1177 (10th Cir. 1985) ("All that the law requires is that the FTC actually had some 'reason to believe'"); *Standard Oil Co. v. FTC*, 596 F.2d 1381, 1386 (9th Cir. 1979), *rev'd on other grounds*, 449 U.S. 232 (1980) (courts should not disturb the agency's reason to believe determination unless "the complaint was issued solely because of some outside pressure or with complete absence of a 'reason to believe' determination"). Although the Supreme Court reversed the Ninth Circuit's holding that issuance of the administrative complaint was final agency action under Administrative Procedure Act, it expressly reserved decision on the scope of judicial review that is not governed by the APA. 449 U.S. at 245 n.13.

least some facts to support a reasonable inference" that the defendants are violating or about to violate the law at the time the suit is brought. *FTC v. Hornbeam Special Situations, LLC*, 391 F. Supp. 3d 1218, 1223 (N.D. Ga. 2019).

B. The complaint plausibly alleges reason to believe Vyera is violating the law

1. The complaint alleges ongoing anticompetitive conduct

The FTC brought suit in January 2020 alleging ongoing violations of Section 5 of the FTC Act. Specifically, the initial complaint (ECF No. 2)[8] alleges that:

- Defendants' "unlawful scheme to maintain a monopoly on Daraprim continues to this day." (Compl. ¶ 1);
- Vyera's current contracts with distributors and purchasers bar the resale of Daraprim to generic companies. *Id*. ¶¶ 94-107 (describing current agreements under which distributors "**cannot** sell Daraprim to generic companies without Vyera's approval" (emphasis added)); *Id.* ¶¶ 113-16 (describing current agreements that "**prevent** [hospitals and pharmacies] from selling Daraprim to generic companies" (emphasis added));
- "The 2017 exclusive supply agreement with Fukuzyu remains in effect" (*id.* ¶ 152) and Vyera paid [redacted] to prematurely terminate the RL Fine agreement less than three months before this lawsuit began *(id*. ¶ 166);
- Vyera's data-blocking agreements with two distributors remain in effect. *Id.* ¶ 180 ("IQVIA's Daraprim data **is** 'extremely incomplete and not very useful." (emphasis added)); *id.* 184 ("The sole purpose of the data-blocking agreements **is** to mask the size of the Daraprim market." (emphasis added)).

[8] Although this brief primarily discusses the allegations in Plaintiffs' April 14, 2020 amended complaint, Defendants' argument that their conduct had ended at the time Plaintiffs filed suit specifically puts at issue the allegations in Plaintiffs' original complaint, filed under seal January 27, 2020. This brief uses "Am. Compl." to refer to the April 14 amended complaint and "Compl." where necessary to refer to the January 27 initial complaint.

- "As a result of Defendants' conduct, there is no generic alternative to Daraprim on the market today." *Id.* ¶¶ 271-73, 282 ("The economic harm from Defendants' conduct is ongoing as generic entry has not yet occurred.").
- Vyera "continues to exercise monopoly power in the United States with respect to Daraprim." *Id.* ¶ 287.

In its prayer for relief, the FTC requested "[t]hat Defendants are permanently enjoined from continuing their course of conduct." *Id.* Prayer for Relief 7. Thus, at the time the FTC filed this case, virtually all of Defendants' anticompetitive agreements were still in place, Vyera continued to exercise monopoly power, and it was uncertain whether and when a generic company would receive FDA approval or enter the market. This is more than sufficient to support a reason to believe Vyera was engaged in ongoing illegal conduct.

2. Vyera's attempt to equate this ongoing conduct with the long-past conduct in *Shire* fails

Vyera's entire challenge to the FTC's authority to bring this suit in federal court rests on the Third Circuit's decision in *FTC v Shire ViroPharma*. 917 F.3d 147. In *Shire*, the FTC sued a pharmaceutical manufacturer over its use of baseless petitions to the FDA to delay generic competition to its leading product. It was undisputed that the challenged conduct had ended nearly five years before the Commission filed its complaint and that Shire had not engaged in any similar conduct in the intervening years. *Id*. at 160. The Third Circuit affirmed dismissal of the case on the ground that Section 13(b) "does not permit the FTC to bring a claim based on long-past conduct without some evidence that the defendant 'is' committing or 'is about to' commit another violation." *Id.* at 156.

As Vyera concedes, however, *Shire*'s interpretation of Section 13(b) permits the FTC to file suit in federal court when it has reason to believe there is ongoing unlawful conduct. Mem.

15-16 ("In the case of **ongoing** or imminent future conduct, under Section 13(b) . . . the FTC may file suit in federal court." (emphasis added)); *see also FTC v. Next-Gen, Inc*., No. 4:18-cv-00128-DGK, 2018 WL 5310414, at *4 n.6 (W.D. Mo. Sept. 10, 2018) ("Even if *Shire* applies and is correctly decided, it has no import because Plaintiffs adequately plead a present or future violation."). And other courts considering *Shire* have declined to dismiss FTC cases when there is any dispute about whether illegal conduct was ongoing at the time of suit. *See FTC v. Educare Centre Servs., Inc*., 433 F. Supp. 3d 1008, 1016-17 (W.D. Tex. 2020) (distinguishing *Shire* given factual dispute about whether conduct had actually stopped before FTC's lawsuit); *In re Sanctuary Belize Litig.*, Civil No. PJM 18-3309, 2019 WL 4243079 (D. Md. Sept. 5, 2019) (declining to dismiss case where existence of ongoing conduct was disputed).

Here, unlike the undisputed facts in *Shire*, the FTC alleges that Vyera has *never* stopped its anticompetitive conduct—despite being aware of the FTC's investigation. Indeed, much of the challenged conduct, such as the two API exclusivity agreements, the data-blocking agreements, and many of the distributor and purchaser restrictions, occurred after the FTC opened its investigation. Most of these agreements remained in place when the FTC filed suit and remain in place today. Despite these allegations, Vyera tries to equate its ongoing conduct with the "long-past" conduct in *Shire*. Mem. 16, 18-20. These efforts fail.

First, Vyera improperly relies on events that occurred *after* this lawsuit began in January 2020. Citing the updated allegations in Plaintiffs' April 2020 amended complaint, Vyera emphasizes the FDA's February 2020 approval of Cerovene's generic Daraprim product and the market entry of that product a month later. *See* Mem. 18, citing Am Compl. ¶¶ 216, 218. But *Shire* requires only that the FTC plead ongoing or impending conduct "*at the time it files suit*." 917 F.3d at 158 (emphasis added); 15 U.S.C. § 53(b) (authorizing FTC to "bring suit" in district

court for injunctive relief when it has reason to believe a defendant is violating the law).[9] When the FTC filed its complaint, whether or when Cerovene would receive FDA approval was uncertain.

Second, Vyera's suggestion that the challenged conduct ended merely because three generic companies had already filed generic applications with the FDA contradicts the complaint. As the complaint allegations make clear, Vyera's anticompetitive scheme can successfully impede and delay potential competitors well after they file their applications. For example, [redacted] submitted its application to the FDA in 2014—before Vyera had even purchased Daraprim. Am. Compl. ¶ 199. But Vyera's anticompetitive conduct caused [redacted] to lose [redacted] API suppliers and spend more than a year trying to obtain Daraprim samples for bioequivalence testing. *Id.* ¶¶ 201-15. [redacted] similarly lost its API supplier due to Vyera's exclusivity agreement after it had filed its ANDA. *Id*. ¶¶ 231-35. Moreover, as the amended complaint makes clear, even Cerovene's FDA *approval* has not ended Vyera's anticompetitive scheme: Vyera's ongoing restrictive agreements [redacted] and continue to impede other potential generic competitors. *Id*. ¶¶ 99-128, 134-36, 158, 220.[10]

Third, Vyera suggests that the lack of a request for "emergent relief" somehow shows there is no ongoing illegal conduct. Mem. 18. But neither *Shire* nor any other authority requires such a request to bring a permanent injunction suit under Section 13(b). As the Ninth Circuit

[9] Plaintiffs' later filing of an amended complaint does not change the prevailing facts at the time the lawsuit was filed. *See, e.g., Educare*, 433 F. Supp. 3d at 1010, 1016 (assessing conduct as of the time of the action's initiation, notwithstanding later filing of an amended complaint); *Sanctuary Belize*, 2019 WL 4243079, at *1-2 (same).

[10] Cerovene entered the market after the FTC's complaint was filed, [redacted] Am. Compl. ¶ 220. [redacted] Vyera's web of resale restrictions [redacted] *Id.*

explained in *FTC v. H.N. Singer*, the grant of authority for permanent injunction suits was intended to allow the FTC to litigate its entire case directly in federal court, rather than its own administrative court, when it finds it more efficient to do so. 668 F.2d 1107, 1111 (9th Cir. 1982). While requests for asset freezes and other types of preliminary relief are common in the FTC's federal court consumer protection suits,[11] that is not so in its antitrust suits. The Commission has repeatedly sued under Section 13(b)'s permanent injunction proviso to address ongoing anticompetitive conduct without seeking any preliminary injunctive relief.[12]

This Court should reject Defendants' attempt to equate the ongoing anticompetitive conduct in this case with the long-past conduct in *Shire*, which undisputedly ceased five years before the complaint was filed.

C. The complaint plausibly alleges reason to believe Vyera is "about to violate" the law

1. Vyera's past conduct strongly indicates that it likely will continue to engage in anticompetitive conduct absent relief

In addition to alleging ongoing conduct, the FTC alleges reason to believe that Vyera is "about to violate" the law because it is likely to engage in similar anticompetitive conduct in the future. The Second Circuit has not squarely interpreted the meaning of "is violating, or is about to violate" in Section 13(b). But it has held that the nearly identical phrase "is engaged or [is] about to engage [in a violation]" in statutes governing Securities and Exchange Commission

[11] When a court issues preliminary relief in a Section 13(b) case seeking a permanent injunction, it acts pursuant to Federal Rule of Civil Procedure 65, not under the first part of Section 13(b), which authorizes preliminary injunctions pending completion of an internal FTC administrative adjudication. *See Singer*, 668 F.2d at 1111; *FTC v. U.S. Oil & Gas Corp*., 748 F.2d 1431, 1434-35 (11th Cir. 1984).

[12] *See, e.g.*, *FTC v. Actavis, Inc.*, 570 U.S. 136 (2013); *FTC v. Surescripts, LLC*, 424 F. Supp. 3d 92 (D.D.C. 2020); *FTC v. Qualcomm Inc.*, 411 F. Supp. 3d 658 (N.D. Cal. 2019); *FTC v. Cephalon, Inc.*, 36 F. Supp. 3d 527 (E.D. Pa. 2014); *FTC v. Mylan Labs. Inc*., 62 F. Supp. 2d 25 (D.D.C. 1999).

suits[13] is satisfied by a past violation combined with a "reasonable likelihood of further violation in the future." *SEC v. Commonwealth Chemical Sec., Inc.*, 574 F.2d 90, 98-99 (2d Cir. 1978) (Friendly, J.). In *Commonwealth Chemical*, the defendants argued that an injunction was improper because the SEC had sued them 15 months after their last violation, and they had "voluntarily terminated all connection with [the securities business] long before the injunction issued." *Id*. at 98. The Second Circuit rejected that argument, holding that "[e]xcept for the case where the SEC steps in to prevent an ongoing violation," the "is . . . or about to" language "seems to require a finding of 'likelihood' or 'propensity' to engage in future violations." *Id*. at 99.[14]

The facts alleged in this case amply support the FTC's "reason to believe" that Vyera is "about to violate" the law. The Commission bases such "reason to believe" determinations on the evidence in its possession at the time and its long experience and expertise enforcing the FTC Act. Here, Vyera's past conduct strongly indicates that it will continue to violate the law. The complaint describes an egregious violation that was deliberate and longstanding. Compl. ¶¶ 80-85; 89-93 (describing 2015 acquisition of Daraprim with plan to implement and maintain a 4,000% price increase). Vyera carried out its anticompetitive scheme with the intent and effect of maintaining monopoly pricing for a lifesaving drug used to treat vulnerable patients. *Id*. ¶¶ 63-68. Moreover, the strategy it used to enrich itself at the expense of Daraprim patients is its entire business model: Vyera was formed to employ this very type of anticompetitive scheme to extract monopoly profits on off-patent pharmaceutical products. *Id*. ¶ 80. Finally, Vyera is actively

[13] *See* 15 U.S.C. §§ 77t(b), 78u(d)(1).

[14] The Supreme Court endorsed the Second Circuit's interpretation of "is . . . or is about to" in *Aaron v. SEC*. 446 U.S. 680, 701 (1980) ("In cases where the [SEC] is seeking to enjoin a person 'about to engage in any acts or practices which . . . will constitute a violation of [the securities laws], the Commission must establish a sufficient evidentiary predicate to show that such future violation may occur.").

seeking to repeat the same tactics with another drug. *Id*. ¶¶ 284-86. Thus, in addition to ongoing illegal conduct, the complaint amply alleges reason to believe Vyera's unlawful conduct is likely to recur. *See SEC v. Mgmt. Dynamics, Inc*., 515 F.2d 801, 807 (2d Cir. 1975) (assessing reasonable likelihood of recurrence based on "the totality of circumstances, and factors suggesting that the infraction might not have been an isolated occurrence are always relevant").[15]

2. Vyera's contention that *Shire* requires the FTC to allege an imminent recurrent violation is without merit

Ignoring the Second Circuit precedent discussed above, Vyera argues that this Court should adopt the Third Circuit's interpretation of "about to violate" in Section 13(b) and require an "imminent" future violation. Mem. 15-16. The Court should not do so.

To begin with, *Shire* expressly declined to equate "about to violate" in the FTC statute with imminence. 917 F.3d at 160 (holding that the FTC failed to state a claim "under any reasonable definition of 'about to violate'"). Instead, the Third Circuit ruled that "Section 13(b) does not permit the FTC to bring a claim *based on long-past conduct* without some evidence that the defendant 'is' committing or 'is about to' commit another violation." *Id.* at 156 (emphasis added). Courts that have since addressed *Shire* have consistently read the decision narrowly and confined to its facts. For example, the court in *Educare* noted that the Third Circuit had "emphasized the factual confines of its ruling" and concluded that *Shire* had simply held that "the alleged misconduct was too far in the past to support the FTC's belief that the defendant was presently violating or about to violate the law." 433 F. Supp. 3d at 1016.[16]

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[15] *See also FTC v. Minuteman Press*, 53 F. Supp. 2d 248, 260-61 (E.D.N.Y. 1998) (listing factors, including the nature and character of past violations, the harm inflicted on consumers, and the sincerity of any assurance against future violations); *FTC v. Magui Publishers, Inc*., Civ. No. 89-3818RSWL(GX), 1991 WL 90895 (C.D. Cal. Mar. 28, 1991) (same).

[16] *See also FTC v. Elec. Payment Sols. of Am., Inc*., No. CV-17-02535-PHX-SMM, 2019 WL 4287298, at *9-11 (D. Ariz. Aug. 28, 2019) (declining to follow *Shire* based on Ninth Circuit precedent and plausible allegations that (Continued…)

Moreover, to the extent that *Shire* interpreted "about to violate" as requiring more than a reasonable likelihood of recurrence, this Court should not follow it because it conflicts with the Second Circuit's reading of the virtually identical "about to engage" language in SEC statutes. *See Commonwealth Chemical*, 574 F.2d at 98-99. *Shire* declined to give any weight to this longstanding judicial interpretation, reasoning that the analogous language of Section 13(b) was so plain that it foreclosed consideration of other statutes. *Id.* at 156-58. This rationale is unpersuasive for three reasons.

First, decades of precedent belie *Shire*'s conclusion that the meaning of Section 13(b)'s "is violating, or is about to violate" is so clear and unambiguous that it forecloses consideration of other statutes. *See* 917 F.3d at 158. For 40 years, courts have repeatedly allowed the FTC to seek and obtain injunctive relief under Section 13(b) for past conduct that ceased prior to suit when there was a reasonable likelihood of recurrence.[17] Until *Shire*, no court had ever denied an FTC claim for a federal court injunction because the complaint did not plead an ongoing or imminent violation. Thus, *Shire* rests on the implausible assumption that every court to consider this language stretching back four decades simply ignored the statute's plain language. The far

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defendants' cessation of their alleged misconduct occurred during the period prior to suit when the government was prosecuting other aspects of the illegal scheme); *FTC v. Hornbeam*, 391 F. Supp. 3d at 1223 (explaining that the "the differing circumstances of the instant case" were sufficient to infer from the defendants' past conduct the requisite "reason to believe" that the they were "about to violate" the law); *FTC v. Adept Mgmt. Inc*., Civ. No. 1:16-cv-00720-CL, 2019 WL 2433193, at *1 (D. Or. June 7, 2019) (rejecting *Shire* "as contrary to well-established precedent in the Ninth Circuit and as distinguishable from the facts in the case at bar"); *FTC v. Agora Fin. LLC*, Civil Case No. 1:19-cv-3100-SAG, 2020 WL 998734, at *13 (D. Md. Mar. 2, 2020) (concluding that, in contrast to *Shire, "*the FTC has 'reason to believe' that Defendants will continue to violate the FTC Act").

[17] *See, e.g., FTC v. Accusearch Inc*., 570 F.3d 1187, 1201-02 (10th Cir. 2009) (injunctive relief warranted in light of past conduct that had ended prior to FTC suit); *FTC v. USA Fin., LLC*, 415 F. App'x 970, 975 (11th Cir, 2011) (permanent injunctive relief appropriate when "the defendant's past conduct indicates that there is a reasonable likelihood of further violations in the future."); *FTC v. Citigroup Inc.*, 239 F. Supp. 2d 1302, 1305-06 (N.D. Ga. 2001) (denying motion to dismiss because complaint sufficiently alleged a likelihood of future violations); *FTC v. Engage-A-Car Servs., Inc*., Civ. A. No. 86-3758, 1986 WL 15066, at *1, *5 (D.N.J. Dec. 18, 1986) (denying motion to dismiss on the basis that the "FTC has failed to allege that [either defendant] is violating or is about to violate any law enforced by the FTC" because the "facts pleaded . . . would support an inference that defendants' § 5 violations are likely to recur").

more likely conclusion is that the text is not plain, but ambiguous, and thus that similar statutory language is properly considered.

Second, the widespread judicial interpretation of the "about to" violate language in SEC statutes was already well established when Congress enacted Section 13(b) in 1973. Courts assume that "when Congress enacts statutes, it is aware of relevant judicial precedent." *Merck & Co. v. Reynolds*, 559 U.S. 633, 648 (2010). In 1959, 14 years before Section 13(b) was enacted, the Second Circuit held in *SEC v. Culpepper* that the "is engaged or about to engage" language in SEC statutes includes situations where a past violation has ceased but there is "a reasonable expectation of further violations." 270 F.2d 241, 250 (2d Cir. 1959). Congress's use of similar language in Section 13(b) should be considered in that context.

Third, the legislative history of Section 13(b) does not support a different interpretation than the Securities and Exchange Act. Congress added Section 13(b) to the FTC Act in 1973 because it determined that the FTC needed additional enforcement tools to adequately protect American consumers. Congress expressed particular concern that under the then-existing regime, which provided for enforcement only through the FTC's administrative process, unfair or deceptive acts or practices "might continue for several years until agency action is completed." S. Rep. No. 93-151, at 30 (1973). It anticipated that "Commission resources will be better utilized, and cases can be disposed of more efficiently" by authorizing the Commission to dispense with the administrative process and instead seek a permanent injunction in district court. *Id.* at 31. This record is consistent with the conclusion that when Congress decided to

expand the FTC's powers, it did so using the same "is . . . or about to" language that had long been understood to encompass past violations that are likely to recur.[18]

II. All Plaintiff States have authority to seek the requested relief

All Plaintiff States' claims are properly brought in federal court. Defendants only take aim at a single claim for each of Pennsylvania and New York. They do not challenge the other Plaintiff States' claims, and they do not challenge New York's other claim (under New York's antitrust law, the Donnelly Act).[19]

A. The Commonwealth of Pennsylvania has properly brought this case in federal court and is authorized to seek the requested relief

Defendants assert that the Commonwealth of Pennsylvania has failed to plead a cognizable violation of the Unfair Trade Practices and Consumer Protection Law ("UTPCPL") and conflate damages with equitable monetary relief under the common law. Their arguments fail for a number of reasons.

First, Defendants misstate the scope of the UTPCPL. The UTPCPL is a remedial statute, to be liberally construed. *Commonwealth v. Monumental Props., Inc.*, 329 A.2d 812, 817 (Pa. 1974). The Pennsylvania Supreme Court has held that the statute is remedial and "broad enough to encompass all claims of unfair and deceptive acts or practices in the conduct of any trade or commerce." *Ash v. Cont'l Ins. Co.*, 932 A.2d 877, 882 (Pa. 2007); *Monumental*, 329 A.2d at 817. One of the broad goals of the UTPCPL is to ensure competitive fairness. *Danganan v. Guardian*

[18] In a footnote, Vyera argues that Section 13(b) does not allow the FTC to seek any form of monetary relief, but does not ask the court to decide this issue. Mem. 20 n.7. As Vyera acknowledges, however, the Second Circuit has squarely rejected this argument. *See FTC v. Bronson Partners, LLC*, 654 F.3d 359 (2d Cir. 2011).

[19] Defendants err to assert that state antitrust law simply follows federal law. Mem. 26-27. This is an incorrect statement of law. *See, e.g.*, *Samsung Elecs. Co. v. Panasonic Corp.*, 747 F.3d 1199, 1205 n.4 (9th Cir. 2014) ("California's antitrust statute [is not] coextensive with the Sherman Act."); *Aryeh v. Canon Bus. Sols., Inc.*, 292 P.3d 871, 877 (Cal. 2013) (Cartwright Act not modeled on federal antitrust statutes); *see also Baker v. Jewel Food Stores, Inc.*, 823 N.E.2d 93, 101 (Ill. App. Ct. 2005).

Prot. Servs., 179 A.3d 9, 16 (Pa. 2018). Pennsylvania's intermediate appellate court recently confirmed the Attorney General's authority to seek remedies under UTPCPL for unfair conduct that is anticompetitive. *Anadarko Petroleum Corp. v. Commonwealth*, 206 A.3d 51, 61 (Pa. Commw. Ct. 2019).

Second, the UTPCPL is a "little-FTC Act" and, just like its federal precursor, it allows the Attorney General to seek remedies for anticompetitive conduct. *See Anadarko*, 206 A.3d at 61. Notwithstanding Defendants' assertion to the contrary, the Commonwealth has alleged "fraudulent or deceptive" conduct, and that conduct "creates a likelihood of confusion or of misunderstanding." In paragraph 351 of the amended complaint and its five subparts, the Commonwealth alleges "constructive fraud" as an unfair method of competition, unfair or deceptive acts or practices, and other allegations squarely within the meaning of the catchall under 73 P.S. § 201-2(4)(xxi). Am. Compl. ¶ 351(a)-(e).

Defendants also interpret "fraud" too narrowly. Fraud has a broader meaning in equity. *SEC v. Capital Gains Research Bureau, Inc.*, 375 U.S. 180, 193 (1963). Fraud in equity includes all acts, omissions and concealments which involve a breach of legal or equitable duty and are injurious to another, or by which an undue and unconscientious advantage is taken of another. *Id.* at 194. The UTPCPL is to be applied remedially to "thwart fraud in the statutory sense" and to be construed liberally "to effect its object of preventing unfair or deceptive practices." *Monumental*, 329 A.2d at 817. The complaint's allegations are sufficient as a matter of law.

Determining what is unfair as constructive fraud involves a variety of factors. *Commonwealth ex rel. Zimmerman v. Nickel*, 26 Pa. D. & C.3d 115, 120-21 (Pa. Ct. Com. Pl. 1983) (citing *FTC v. Sperry and Hutchinson Co.*, 405 U.S. 233, 244-45 n. 5 (1972)); *Westfield Grp. v. Campisi*, No. 2:02CV997, 2006 WL 328415, at *18 (W.D. Pa. Feb. 10, 2006) (an act or

practice need not be deceptive to be declared "unfair"). A plaintiff "need not establish every factor." *See Cheshire Mortg. Serv., Inc. v. Montes*, 612 A.2d 1130, 1143-44 (1992); *see also Long v. Dell, Inc.*, 93 A.3d 988, 1001 (R.I. 2014). Pervasive illegal conduct constitutes unfair conduct within the meaning of the catchall provision of the UTPCPL. *In re Milbourne*, 108 B.R. 522, 534 (Bankr. E.D. Pa. 1989). Indeed, pervasive illegal conduct includes violations of laws intended to protect consumers and the public interest, such as the laws alleged in the amended complaint. ¶ 351(a)-(e); *see, e.g., Nickel*, 26 Pa. D. & C.3d at 120-21; *In re Rodriguez*, 218 B.R. 764, 784 (Bankr. E.D. Pa. 1998).

Third, Defendants err to argue that the Commonwealth may not pursue UTPCPL violations based on past illegal activities. *Commonwealth v. Percudani*, 844 A.2d 35, 46 (Pa. Commw. Ct. 2004), *as amended* (Apr. 7, 2004), *opinion amended on reconsideration,* 851 A.2d 987 (Pa. Commw. Ct. 2004). Pennsylvania courts have recognized that limiting the Commonwealth's actions to ongoing activities would frustrate the purpose of the UTPCPL. *Id.* And regardless, as described above, the misconduct here is ongoing.

Finally, Defendants mistakenly rely on authorities concerning Pennsylvania private plaintiffs who were not allowed to sue for damages under the common law. Mem. 22-23. Defendants cannot cite any case that precludes the Commonwealth from seeking monetary equitable relief under Pennsylvania antitrust common law. On the contrary, the Commonwealth can seek equitable relief for a violation of antitrust common law. Order on Preliminary Objections, *Commonwealth v. Chesapeake Energy, Inc. et al.*, No. 2015IR0069 (Bradford County Ct. Com. Pl., Dec. 14, 2017); *see also Solomon v. Cedar Acres E., Inc.*, 455 Pa. 496, 501 (1974) (equity provides complete relief and complete justice).

B. New York is authorized to enforce N.Y. Executive Law § 63(12) against defendants for their anticompetitive scheme

The New York Attorney General may seek equitable relief for (1) "repeated fraudulent or illegal acts" or (2) "persistent fraud or illegality in the carrying on, conducting or transaction of business." N.Y. Exec. Law § 63(12). The statute defines "repeated" to mean *either* "repetition of any separate and distinct fraudulent or illegal act" *or* "conduct which affects more than one person." *Id.* The term "persistent fraud or illegality" is defined to include "continuance or carrying on of any fraudulent or illegal act or conduct." *Id.* New York alleges and satisfies these statutory definitions. Am. Compl. ¶ 328.

New York alleges "repeated" bad acts, such as that "Vyera has denied *each request* from a distributor to sell Daraprim to a purchaser that might be a generic company." *Id.* ¶ 113 (emphasis added). New York also alleges "conduct which affects more than one person," which—by statutory definition—is a "repeated" act. *Id*. ¶ 281 (economic harm to consumers "and other purchasers").

The allegations also satisfy both common sense and statutory definitions of "persistent fraud or illegality." Plaintiffs allege several kinds of ongoing misconduct that persisted when this case was filed and still persist today despite FDA approval of a single generic. *See* Am. Compl. ¶¶ 101-113, 119-122, 127, 135 (distribution restrictions impeding additional entrants); *id.* ¶¶ 153, 156-58 (supply restrictions). The complaint also alleges specific ongoing acts, each of which satisfies the statutory definition. *See, e.g.*, *id*. ¶ 158 (Vyera's "exclusive supply agreement . . . remains in effect"); *id*. ¶ 99 ("web of contractual restrictions prevents generic companies from . . . conduct[ing] the bioequivalence testing necessary for FDA approval"). Indeed, there is even an allegation that [redacted]—and on which Defendants'

motion is entirely based—[redacted] the anticompetitive supply restrictions. *Id.* ¶ 220.

Case law supports New York, not Defendants. All the Attorney General is required to show is any number of "separate and distinct fraudulent or illegal acts which affected more than one individual." *People v. 21st Century Leisure Spa Int'l Ltd.*, 153 Misc. 2d 938, 944 (N.Y. Sup. Ct. 1991). Even voluntary discontinuance of misconduct is insufficient to deny an injunction, much less here, where Defendants continue to engage in their misconduct. *See*, *e.g.*, *People v. Greenberg*, 27 N.Y.3d 490, 496-497 (N.Y. 2016); *People v. Orbital Publ'g Grp., Inc.*, 169 A.D.3d 564, 565 (N.Y. App. Div. 2019); *People v. Gen. Elec. Co.*, 302 A.D.2d 314, 316 (N.Y. App. Div. 2003); *State v. Midland Equities of N.Y., Inc.*, 458 N.Y.S.2d 126, 128-9 (N.Y. Sup. Ct. 1982); *Matter of State of New York v. Person*, 75 Misc. 2d 252 (N.Y. Sup. Ct. 1973).

The cases cited by Defendants do not support their motion. In *State v. Magley*, 484 N.Y.S.2d 251, 253 (N.Y. App. Div. 1984), the court affirmed discretionary denial of an injunction by the court below because the alleged misconduct that the plaintiff sought to stop was the defendants' exercise of their constitutional protected right to seek redress in a court of law. There is no equivalent allegation here, and there is no right to exclusionary and restrictive contractual provisions tailored to monopolize. The other authorities cited by Defendants do not address pertinent issues. *See, e.g.*, *Tyler v. Douglas*, 280 F.3d 116, 122 (2d Cir. 2001) (statutes are interpreted according to "plain language"); *People v. Dorsey*, 29 N.Y.S.2d 637, 643 (Queens Co. Ct. 1941) (Section 63(12) was not intended to "revolutionize our criminal procedure"); *see also* Mem. 24-25 (discussing legislative history of Section 63(12), and dictionary definition of the word "shall").

III. The complaint states valid claims of monopolization

A monopolization claim under Section 2 of the Sherman Act has two elements: (1) the possession of monopoly power in the relevant market and (2) anticompetitive conduct—"the willful acquisition or maintenance of that power as distinguished from growth or development as a consequence of a superior product, business acumen, or historic accident." *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, 504 U.S. 451, 481 (1992) (citation and internal quotation marks omitted); *New York ex rel. Schneiderman v. Actavis plc*, 787 F.3d 638, 651 (2d Cir. 2015) ("*Namenda II*").[20] Vyera's motion does not challenge Plaintiffs' allegations of monopoly power. Thus, the question before the Court is whether Plaintiffs' complaint plausibly alleges that Vyera illegally maintained its monopoly through anticompetitive conduct.

Anticompetitive conduct "can come in too many different forms, and is too dependent upon context, for any court or commentator ever to have enumerated all the varieties." *Caribbean Broad. Sys., Ltd. v. Cable & Wireless PLC*, 148 F.3d 1080, 1087 (D.C. Cir. 1998). But several key principles are well established. First, a monopolist's conduct is anticompetitive or exclusionary if it "impedes competition through means other than competition on the merits." *Namenda II*, 787 F.3d at 652; *see also United States v. Microsoft Corp.*, 253 F.3d 34, 65 (D.C. Cir. 2001). And conduct that might be permissible in a competitive market "may be impermissibly exclusionary when practiced by a monopolist." *United States v. Dentsply Int'l, Inc.*, 399 F.3d 181, 187 (3d Cir. 2005); *see also Microsoft*, 253 F.3d at 70.

Second, courts generally apply the antitrust rule of reason to evaluate allegedly anticompetitive conduct. *Namenda II*, 787 F.3d at 652. The rule of reason analysis entails a

[20] The FTC brings its claims pursuant to the FTC Act. Plaintiff States bring claims under the Sherman Act as well as various state statutes. Substantively, however, these claims all challenge monopolization within the meaning of Section 2 of the Sherman Act or agreements in restraint of trade within the meaning of Section 1 of the Sherman Act. For ease of reference, Plaintiffs thus refer to their claims as "Section 1" or "Section 2" claims.

three-step, burden-shifting framework, in which (1) the plaintiff bears an initial burden to show anticompetitive effects, (2) the defendant then must demonstrate a procompetitive rationale for the challenged conduct, and (3) the burden shifts back to the plaintiff to show that the procompetitive benefits could be achieved through less anticompetitive means. *Ohio v. American Express Co.*, 138 S. Ct. 2274, 2284 (2018); *Namenda II*, 787 F.3d at 652. A plaintiff can satisfy its initial burden in two ways: with proof of "actual detrimental effects on competition" or indirectly, with "proof of market power plus some evidence that the challenged restraint harms competition." *American Express*, 138 S. Ct. at 2284 (internal quotation omitted).

Third, in addition to purely unilateral conduct, Section 2 also reaches a monopolist's use of agreements with others to acquire or maintain a monopoly. *See*, *e.g.*, *Geneva Pharm. Tech. Corp. v. Barr Labs. Inc.*, 386 F.3d 485, 501 (2d Cir. 2004) (monopolization claim based on pharmaceutical manufacturer's exclusive agreement with API supplier); *Microsoft*, 253 F.3d at 70 (monopolization claim based on exclusive contracts that impeded competitor). Indeed, although Sections 1 and 2 of the Sherman Act have distinct elements,[21] the analysis of anticompetitive conduct is similar under both. *See Microsoft*, 253 F.3d at 59 ("[T]he analysis under section 2 is similar to that under section 1."); *E & L Consulting, Ltd. v. Doman Indus. Ltd.*, 472 F.3d 23, 31 (2d Cir. 2006) ("A viable claim under Section 2 challenging a distributorship agreement must, like a Section 1 claim, show harm to competition."). To the extent there is a difference, "[t]he standard for exclusive dealing under Section Two of the Sherman Act is lower than under Section One." *Dial Corp. v. News Corp.*, 165 F. Supp. 3d 25, 36 (S.D.N.Y. 2016); *see also Microsoft*, 253 F.3d at 70.

[21] Section 2 requires monopoly power, which is not challenged here. Section 1 requires an agreement between two legally distinct entities, as discussed further in Part IV.

A. The complaint plausibly alleges that Vyera's resale-restriction agreements are anticompetitive and exclusionary

1. The resale-restriction agreements impede potential generic competitors from obtaining FDA approval

The complaint amply alleges that Vyera's resale restrictions "impede[] competition through means other than competition on the merits." *Namenda II*, 787 F.3d at 652. Vyera maintains an extensive web of agreements that block generic companies from purchasing Daraprim at every level of the distribution chain. Under these restrictive agreements, distributors, as well as downstream purchasers such as hospitals and pharmacies, cannot sell Daraprim to anyone that is not authorized by Vyera. Am. Compl. ¶¶ 100-22. Even for authorized buyers, Vyera's agreements limit the quantity available to any particular customer. *Id.* ¶¶ 123-29. And Vyera aggressively monitors sales to ensure compliance with these restrictions. In one instance, this monitoring revealed that a distributor had inadvertently sold Daraprim to an unknown purchaser. To prevent the Daraprim from being resold to a generic, Vyera bought it back at [redacted] the original price. *Id.* ¶¶ 130-32.

Taken together, the purpose and effect of these restrictions, the complaint alleges, is to prevent generic companies from obtaining sufficient quantities of Daraprim to conduct the bioequivalence testing required for FDA approval. *Id.* ¶¶ 134-37. This effect is not speculative: multiple generic competitors have been substantially delayed in obtaining FDA approval because they could not purchase enough Daraprim for bioequivalence testing. *Id.* ¶¶ 207-13, 248-54. As the complaint further alleges, these restrictions have no legitimate business purpose or rationale. *Id.* ¶¶ 141-43. Indeed, due to Vyera's enormous profit margin on Daraprim, its extensive efforts to restrict Daraprim sales are economically irrational aside from their anticompetitive effect. *Id.* ¶¶ 113, 122.

Courts have recognized that agreements like these—in which a manufacturer prevents its distributors or purchasers from dealing with a rival—can be anticompetitive and should be analyzed under the rule of reason. In *In re Keurig Green Mountain Single-Serve Coffee Antitrust Litigation*, Keurig allegedly entered into hundreds of "exclusive and restrictive agreements with various entities involved in the line of manufacture and distribution" of Keurig's products. 383 F. Supp. 3d 187, 214 (S.D.N.Y. 2019). These agreements prevented Keurig's distributors and purchasers from selling competitors' products and "limited the ability" of other coffee brands to "provide inputs to" Keurig's competitors. *Id.* Denying Keurig's motion to dismiss, the court held that these restrictive agreements "adequately allege[d] a vertical group boycott." [22] *Id.* at 245-46. *See also Redbox Automated Retail LLC v. Universal City Studios LLLP*, Civil No. 08-766 (RBK), 2009 WL 2588748, at *4-5 (D. Del. Aug. 17, 2009) (recognizing cognizable "vertical boycott" claim where Universal induced its distributors and retailers "not to sell Universal DVDs to Redbox").[23] Plaintiffs' challenge to the similar restrictions here likewise states a claim under the rule of reason.

2. Defendants' "no duty to deal" argument fundamentally misunderstands the nature of Plaintiffs' claims

Defendants do not challenge these allegations directly. Instead, they insist that their conduct is not subject to analysis under the rule of reason because it falls within "the long recognized right of a trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal." Mem. 27-28

[22] Like other vertical restraints, vertical boycotts, which involve "agreements among persons or organizations at different levels of the market structure not to deal with other market participants," are evaluated under the rule of reason. *Moccio v. Cablevision Sys. Corp.*, 208 F. Supp. 2d 361, 378-79 (E.D.N.Y. 2002).

[23] *See also Spectators' Commc'n Network Inc. v. Colonial Country Club*, 253 F.3d 215, 225 (5th Cir. 2001) (holding that the defendant's agreement with the plaintiff's competitor not to deal with the plaintiff could be "a vertical boycott constituting an unreasonable restraint of trade under the rule of reason").

(quoting *Verizon Commc'ns Inc. v. Law Offices of Curtis V. Trinko, LLP*, 540 U.S. 398, 408 (2004) and *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919)). The right described in *Trinko* and *Colgate*, however, does not extend to restraining the dealing of *other* firms. It "applies only to single, not multiple, actors—to unilateral, not concerted action." *Buccaneer Energy Inc. v. Gunnison Energy Corp.*, 846 F.3d 1297, 1309 (10th Cir. 2017); *see also Anderson News, LLC v. American Media, Inc.*, 680 F.3d 162, 183 (2d Cir. 2012) (manufacturer only has a right to refuse to deal "*as long as it does so independently*") (internal quotation marks omitted) (emphasis in original). Put another way, while a company may have a right to choose its own customers, it has no such right to contractually restrict its customers' customers.[24]

The Supreme Court explained this distinction in *Colgate*. 250 U.S. 300. Colgate, a seller of soaps and toilet articles, specified the prices at which its products should be re-sold and informed its wholesalers and retailers that it would no longer do business with anyone that deviated from those announced prices. The Court upheld this practice as a legitimate exercise of Colgate's "independent discretion as to parties with whom [it] will deal." *Id.* at 307. But the Court distinguished this type of unilateral refusal to deal from the use of "contracts which undertook to prevent dealers from freely exercising the right to sell." *Id.* at 307-08.[25] As the Court explained, Colgate's conduct was acceptable because "[n]o suggestion is made that [it] . . .

[24] Even when a company is acting purely unilaterally, its right to refuse to deal is not absolute. *See Trinko*, 540 U.S. at 408 ("[T]he high value that we place on the right to refuse to deal with other firms does not mean that the right is unqualified."). However, because Plaintiffs here challenge Vyera's use of resale-restriction agreements rather than a unilateral refusal to sell Daraprim directly to generic companies, the Court need not address whether Vyera would have a right to refuse to deal if it acted entirely on its own.

[25] The practice of a manufacturer and distributor agreeing on the price set by the distributor, known as resale price maintenance, was a *per se* antitrust violation for more than a century. In 2007, the Supreme Court held that vertical resale price maintenance agreements should instead be evaluated under the rule of reason. *Leegin Creative Leather Prods., Inc. v. PSKS, Inc.*, 551 U.S. 877 (2007). Despite this intervening ruling, *Colgate* and other resale price maintenance cases remain good law insofar as they address the distinct legal treatment afforded to unilateral and concerted action in the type of vertical distribution relationships alleged here. *See Trinko*, 540 U.S. at 408 (citing *Colgate*); *In re Adderall XR Antitrust Litig.*, 754 F.3d 128, 134 (2d Cir. 2014) (citing *Colgate*); *Anderson News,* 680 F.3d at 183 (citing *Monsanto Co. v. Spray-Rite Service Corp.*, 465 U.S. 752, 761 (1984)).

attempted to reserve or retain any interest in the goods sold, or to restrain the vendee in his right to barter and sell the same without restriction." *Id.* at 305-06. In the decades after *Colgate*, the Supreme Court repeatedly reaffirmed this rule: irrespective of any right to independently refuse to deal directly with other parties, a seller may not "destroy [its] dealers' independent discretion through restrictive agreements" *United States v. A. Shrader's Son, Inc.*, 252 U.S. 85, 98 (1920).[26]

The Supreme Court's more recent precedent continues to differentiate unilateral refusals to deal from restraints on others. In *Eastman Kodak Co. v. Image Tech. Servs., Inc.*, the Court rejected Kodak's argument that a tying agreement in which Kodak would sell replacement parts to third parties "only if they agreed not to buy service from [Independent Service Operators]," was equivalent to "a unilateral refusal to deal." 504 U.S. at 463 & n.8. As the Court explained, "[a]ssuming, *arguendo*, that Kodak's refusal to sell parts to any company providing service can be characterized as a unilateral refusal to deal, its alleged sale of parts to third parties on condition that they buy service from Kodak is not." *Id.* at 463 n.8.

In *Trinko*, the Court further "acknowledged th[e] distinction [between unilateral and concerted action] when it rejected the plaintiff's reliance on two early concerted-refusal-to-deal cases." *Buccaneer Energy*, 846 F.3d at 1309 (discussing *Trinko*, 540 U.S. at 410 n.3). Citing *Colgate*, the Court explained that it had been cautious in applying Section 2 to unilateral refusals to deal "because of the uncertain virtue of forced sharing and the difficulty of identifying and remedying anticompetitive conduct *by a single firm*." 540 U.S. at 408 (emphasis added). But

[26] *See*, *e.g.*, *Monsanto*, 465 U.S. at 761 ("Under *Colgate*, the manufacturer can announce its resale prices in advance and refuse to deal with those who fail to comply."); *United States v. Parke, Davis & Co.*, 362 U.S. 29, 44 (1960) (manufacturer may not "go beyond mere announcement of his policy and the simple refusal to deal, and [] employ[] other means" to control how its distributors sell a product); *United States v. Bausch & Lomb Optical Co.*, 321 U.S. 707, 722 (1944) ("[The seller] may not, consistently with the act, go beyond the exercise of this right, and by contracts or combinations, express or implied, hinder or obstruct the free and natural flow of commerce.").

"*Trinko* simply does not speak to claims, like those here, alleging concerted refusals to deal." *Buccaneer Energy*, 846 F.3d at 1309.

In this case, Defendants did not simply refuse to sell Daraprim directly to generic companies or state a policy that distributors should not do so. Instead, they "sign[ed] agreements with the distributors, hospitals, and pharmacies that purchased Daraprim barring resale of the drug to generic companies," creating a "web of contractual restrictions [that] prevents generic companies from purchasing Daraprim at any point in the distribution chain." Am. Compl. ¶ 99. Thus, unlike *Colgate* and *Trinko*, Defendants entered "contracts which undertook to prevent dealers from freely exercising the right to sell." *Colgate*, 250 U.S. at 307-08.[27]

Defendants dismiss Vyera's extensive use of restrictive agreements as "a distinction without a difference" and claim that *Trinko* and *Colgate* shield these agreements from scrutiny under the rule of reason. Mem. 27-29. But this argument runs headlong into decades of contrary Supreme Court and Second Circuit precedent. In *Leegin Creative Leather Products, Inc. v. PSKS, Inc.* and *Continental T.V. Inc. v. GTE Sylvania Inc.*, the Supreme Court held that restrictions in vertical distribution agreements are evaluated under the rule of reason. *See Leegin*, 551 U.S. at 907 ("Vertical price restraints are to be judged according to the rule of reason."); *Continental T.V., Inc. v. GTE Sylvania Inc.*, 433 U.S. 36, 59 (1977) (vertical non-price restraints, such as restrictions on where dealers can sell, are evaluated under the rule of reason). In *Eiberger v. Sony Corp. of America*, the Second Circuit affirmed antitrust liability for contractual restrictions that prevented distributors from re-selling to certain customers. 622 F.2d 1068, 1080-81 (2d Cir. 1980). In *Oreck Corporation v. Whirlpool Corporation*, the Second Circuit remanded

[27] In addition, Defendants took other affirmative steps, including buying back inventory at exorbitant cost, to ensure that no bottles of Daraprim slipped through their web of restrictive agreements and ended up with a potential generic competitor. Am. Compl. ¶¶ 131-32.

a claim challenging a manufacturer-distributor agreement to "be tested by the rule of reason." 579 F.2d 126, 133-34 (2d Cir. 1978). And in *E & L Consulting, Ltd. v. Doman Industries Ltd.*, the primary case upon which Defendants rely, the Second Circuit applied the rule of reason to evaluate whether the challenged distribution contract was unreasonably anticompetitive. 472 F.3d at 29 (finding that plaintiff had not adequately alleged anticompetitive effects).[28] Defendants disregard this long line of precedent and fail to cite a single case shielding a seller's restrictive agreements with other parties from antitrust scrutiny based on a right to refuse to deal.[29]

B. The complaint plausibly alleges that Vyera's exclusive API agreements are anticompetitive and exclusionary

As the Second Circuit explained in *Geneva Pharmaceuticals Tech. Corp. v. Barr Laboratories*, "[e]xclusive dealing arrangements implicate [the antitrust laws] because they have the potential unreasonably to exclude competitors or new entrants from a needed supply." 386 F.3d at 508.[30] The relevant inquiry is whether the agreements "freeze[] out a significant fraction

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[28] Contrary to Vyera's suggestion (Mem. 29), *E & L Consulting* does not address the issue of whether a company has a right to refuse to deal and does not cite *Trinko* or *Colgate*. Instead, the Second Circuit analyzed the plaintiff's factual allegations under the rule of reason and found that the defendant's mere alleged use of a single exclusive distributor instead of multiple distributors was not anticompetitive because it did not enhance or maintain the manufacturer's monopoly power. 472 F.3d at 31 (noting that distribution agreement "provides no monopolistic benefit to Doman"); *see also New York v. Actavis PLC*, No. 14 Civ. 7473, 2014 WL 7015198, at *42 (S.D.N.Y. Dec. 11, 2014) ("*Namenda I*") (noting that plaintiff in *E & L Consulting* had "failed to plead that concerted action would yield an adverse effect on the market"). In contrast, the complaint here amply alleges that Defendants "are relying on [agreements] to maintain their market power." *Namenda I*, 2014 WL 7015198, at *42.

[29] Other than *Oreck*, discussed above, all of the cases cited by Defendants are inapplicable here because they address independent and unilateral refusals to deal directly with other parties. *See*, *e.g.*, *Trinko*, 540 U.S. at 407-08 (defendant refused to allow competitors direct access to its telecommunications network); *Adderall XR*, 754 F.3d at 134-35 (defendant refused to supply its pharmaceutical product directly to its competitors); *In re Elevator Antitrust Litig.*, 502 F.3d 47, 50 (2d Cir. 2007) (no "plausible grounds to infer an agreement" between defendant elevator companies, which each independently refused to deal directly with elevator maintenance providers); *Cinema Vill. Cinemart, Inc. v. Regal Entm't Grp.*, No. 15-cv-05488 (RJS), 2016 WL 5719790, at *3 (S.D.N.Y. Sept. 29, 2016), *aff'd*, 708 F. App'x 29 (2d Cir. 2017) (complaint failed to allege an agreement between film distributors, which each independently refused to license their first-run films to plaintiff theater).

[30] Though the Second Circuit has described exclusive supply agreements as "presumptively legal" (Mem. 31-33 (quoting *CDC Techs., Inc. v. IDEXX Labs., Inc.*, 186 F.3d 74, 80 (2d Cir. 1999)), it has "never held that all exclusive (Continued…)

of . . . sellers from the market." *Id.*; *see also Keurig*, 383 F. Supp. 3d at 234 ("To state a Section 2 claim based on exclusive dealing arrangements, a plaintiff must allege as a threshold matter a substantial foreclosure of competition in the relevant market.").

The complaint plausibly alleges that Vyera's exclusive API agreements "freeze out" the two most viable suppliers of pyrimethamine API, thereby impeding potential generic competitors from securing an essential ingredient of generic Daraprim and forcing them to spend substantial time and money to develop an alternate supplier. Specifically, the complaint alleges that:

- Defendants entered into exclusivity agreements with Fukuzyu and RL Fine to prevent them from selling pyrimethamine API to potential generic competitors (Am. Compl. ¶¶ 152-54, 159, 165, 167-68);
- Fukuzyu was the only supplier already approved to supply pyrimethamine API for use in the United States (*id*. ¶¶ 149-51), and RL Fine was actively working with two generic companies and had a pyrimethamine API manufacturing process that was approved for use in the European Union (*id.* ¶ 160);
- Although other manufacturers might eventually be able to supply pyrimethamine API for the U.S. market, these potential manufacturers "did not have an established pyrimethamine manufacturing process, did not have facilities and processes in line with cGMP standards sufficient for FDA approval, or both" (*id.* ¶ 173);
- By "sidelin[ing] the two most viable suppliers of pyrimethamine API" Vyera's exclusive agreements make "it significantly more difficult for potential generic competitors to obtain pyrimethamine API" (*id.* ¶ 173); and

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arrangements are reasonable as a matter of law." *E & L Consulting*, 472 F.3d at 29-32 (applying rule of reason to exclusive distribution agreement); *see also Geneva Pharm.*, 386 F.3d at 506-10; *CDC Techs.*, 186 F.3d at 80 (applying rule of reason to exclusive distributorship).

- As a result of Vyera's exclusive agreements, three potential generic companies each had to spend more than a year working with new API suppliers to develop pyrimethamine manufacturing processes. (*id.* ¶¶ 173-75, 202-05; 235-37, 243-47).

Vyera erroneously contends that these detailed and specific allegations are insufficient because the complaint does not categorically allege that "there were no other manufacturers capable of supplying pyrimethamine or that prospective generic competitors were incapable of manufacturing their own pyrimethamine API." Mem. 32. But a monopolist's anticompetitive exclusion of a rival can be unlawful even if rivals are not "completely blocked." *Microsoft*, 253 F.3d at 64; *see also Keurig*, 383 F. Supp. 3d at 237 (plaintiff need not allege a "numerator and denominator" for foreclosure to state exclusive dealing claim). As the Second Circuit has explained, "[f]or there to be an antitrust violation, generics need not be barred 'from all means of distribution' if they are 'bar[red] . . . from the cost-efficient ones." *Namenda II*, 787 F.3d at 656 (internal quotations omitted); *see also Dentsply*, 399 F.3d at 191 ("The test is not total foreclosure, but whether the challenged practices bar a substantial number of rivals or severely restrict the market's ambit.").[31]

The facts in *Geneva Pharmaceuticals* illustrate this principle. In that case, Geneva alleged that Barr, another generic company, acquired and maintained a monopoly in the generic warfarin market by entering an exclusive supply agreement with ACIC/Brantford, the most viable source of API. 386 F.3d at 494. Like RL Fine, ACIC/Brantford had promised to sell API to a potential generic competitor (Geneva), but backed out of the deal after signing an exclusivity

[31] Contrary to Defendants' claim, there is no inconsistency between the allegations that Fukuzyu and RL Fine were the two most viable suppliers of pyrimethamine API and that RL Fine never conformed its manufacturing process to FDA requirements. Mem. 32 n.23. The complaint specifically alleges that RL Fine did not take any further steps to conform its process to FDA requirements *after signing the exclusivity agreement with Vyera*. Am. Compl. ¶¶ 165, 169. Prior to that point, it was actively working to supply two potential generic competitors. *Id.* ¶ 160.

agreement with the incumbent (Barr). *Id.* at 493. And like the generic companies in this case, Geneva was then forced to work with a different API supplier that did not have a manufacturing process, assisted the new supplier in developing such a process, and ultimately entered the market "after a one-year delay." *Id.* at 493-94. Despite the availability of other possible API suppliers and Geneva's eventual entry, the Second Circuit held that these facts sufficiently established that "the exclusive dealing arrangement had the potential to freeze competitors out of the generic warfarin sodium market." *Id.* at 508-09; *see also Fresenius Kabi USA, LLC v. Par Sterile Prods., LLC*, Civil Action No. 16-4544 (SDW) (LDW), 2017 WL 548944, at *3-4 (D.N.J. Feb. 10, 2017) (denying motion to dismiss Section 1 and Section 2 claims challenging exclusive API supply agreements with only viable suppliers); *In re Lorazepam & Clorazepate Antitrust Litig.*, 467 F. Supp. 2d 74, 82-84 (D.D.C. 2006) (API exclusivity agreements caused substantial foreclosure when generic competitors had to spend approximately one year developing an alternate supplier).

Defendants' remaining arguments are also misplaced. First, Defendants argue that the contracts with Fukuzyu and RL Fine were "of short duration and [] easily terminable." Mem. 33. The antitrust analysis of foreclosure, however, turns not on the facial terms of the contract, but on the contract's "practical effect" on competition. *Tampa Elec. Co. v. Nashville Coal Co*., 365 U.S. 320, 326 (1961). Exclusive dealing can harm competition even if the contracts are "nonbinding . . . short-term and voluntary"[32] or "terminable on short notice on their face"[33]—so long as the "practical effect" of the conduct is to foreclose rivals from competing. The cases

[32] *McWane, Inc. v. FTC*, 783 F.3d 814, 833-35, 840 (11th Cir. 2015) (holding that exclusive dealing program harmed competition despite being "nonbinding . . . short-term and voluntary," and stating that "these characteristics do not render the program presumptively lawful").

[33] *Masimo Corp. v. Tyco Health Care Grp., L.P.*, No. CV 02-4770 MRP, 2006 WL 1236666, at *6 (C.D. Cal. Mar. 22, 2006) (contracts that are "terminable on short notice on their face" may not be terminable "in practice" and thus can be "de facto exclusive").

Defendants cite are not to the contrary. There, the exclusive dealing claims failed not because of the objective contract terms, but because the agreements did not result in substantial foreclosure in any relevant market.[34]

Second, Defendants' suggestions that exclusive supply agreements are common and procompetitive are nothing more than factual disputes. Mem. 30-32. The complaint specifically alleges that there was nothing common about the RL Fine exclusivity agreement because Vyera "did not need and was not seeking an additional source" of supply, and the amount paid to RL Fine to serve as a secondary supplier [redacted] the amount Vyera paid for its primary supply source. Am. Compl. ¶¶ 164-71. The facts alleged by Plaintiffs amply support an inference that the exclusivity agreements here are not procompetitive. And the resolution of "a factual dispute is not appropriate on a motion to dismiss." *Egelston v. The Valspar Corp*., No. 15cv4130 (DLC), 2015 WL 6508329, at *5 (S.D.N.Y. Oct. 13, 2015) (Cote, J.).

C. The complaint plausibly alleges that Vyera's data-blocking agreements are anticompetitive and exclusionary

Plaintiffs plausibly allege that Vyera's data-blocking agreements with two of its distributors impede generic competitors. The sole purpose of these agreements was to deter competition by obscuring the size of the Daraprim market to make it less attractive to generic competitors. At least one court has found that this type of indirect deterrence can state an antitrust claim. *See United States ex rel. Krahling v. Merck & Co.*, 44 F. Supp. 3d 581, 598-99 (E.D. Pa. 2014) (holding that Merck's alleged misrepresentations to the FDA overstating the

[34] *See, e.g. CDC Techs.,* 186 F.3d at 80-81 (dismissing exclusive dealing claim because there were no "significant barriers to entry," and the plaintiff "successfully reached customers" through alternative distribution channels"); *Balaklaw v. Lovell*, 14 F.3d 793, 798-800 (2d Cir. 1994) (dismissing challenge to exclusive dealing contract between a hospital and a competing anesthesiologist because contract did not foreclose competition in a broader market); *Spinelli v. Nat'l Football League*, 96 F. Supp. 3d 81, 117 (S.D.N.Y. 2015) (dismissing challenge to NFL exclusive licensing agreements that foreclosed only a small fraction of the market); *Wellnx Life Scis. Inc. v. Iovate Health Scis. Research Inc.*, 516 F. Supp. 2d 270, 293 (S.D.N.Y. 2007) (dismissing claims because "[a]ll other competitors compete[d] unobstructed, and even [the plaintiff] remain[ed] free to compete in 30% of the market").

efficacy of its vaccine deterred competitive entry and secured Merck's monopoly).[35] And Vyera's data-blocking agreements worked as intended: Mylan, one of the world's largest generic companies, abandoned its pursuit of a generic Daraprim product, citing in part its inability to get a sense of Daraprim's sales due to the incomplete data reporting. Am. Compl. ¶ 266.

Defendants argue that the data-blocking claim is "facially implausible" because "the price and volume of Daraprim sales—the only two metrics conceivably relevant to assessing the market opportunity—were readily available." Mem. 34-35. So, according to Defendants, Vyera solicited and entered into agreements to pay its distributors for nothing because the information they suppressed was "readily available" from public sources. Not only is this counter-narrative itself implausible, but it also impermissibly contradicts the complaint: Plaintiffs allege that the purpose of the agreements was to deter competitors (Am. Compl. ¶¶ 188, 190) and that they had their intended effect by deterring a specifically-named company from pursuing generic Daraprim. *Id.* ¶¶ 263, 266. These factual allegations, which must be taken as true and all reasonable inferences drawn in Plaintiffs' favor, are sufficient "to state a claim that is plausible on its face." *See Nicosia*, 834 F.3d at 230 (quoting *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009)).

Vyera also misleadingly refers to the distributors' data as "*its* competitively sensitive pricing and sales data" and asserts that generic companies have no "independent right to that information." Mem. 34 (emphasis added). As the complaint alleges, though, the suppressed data belongs to the distributors, not Vyera; that is why Vyera must pay them to suppress it.[36] Am.

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[35] *See also Microsoft*, 253 F.3d at 76-77 (recognizing antitrust violation based on Microsoft's deceptive misrepresentations to third-party software developers that its software development tools were compatible with middleware created by a competitor).

[36] Defendants note that, in other antitrust cases based on different legal theories, sharing sales information (as opposed to suppressing it) has been shown to facilitate anticompetitive conduct. Mem. 34. Be that as it may, this case alleges that Vyera's data-blocking agreements with its distributors were anticompetitive. By blocking dissemination of information that generic drug manufacturers routinely use to identify attractive markets for generic entry, the agreements deterred and delayed generic competition. Am. Compl. ¶¶ 176-78, 188-90.

Compl. ¶ 190. And prior to the data-blocking agreements, the distributors regularly sold their Daraprim sales data to IQVIA and other aggregators. Am. Compl. ¶¶ 178, 190. It is therefore reasonable to infer they would have continued to do so absent Vyera's agreements.

D. Vyera's various anticompetitive agreements are appropriately evaluated together as an overall scheme to impede generic competition

As described above, each aspect of Vyera's scheme—resale-restriction agreements to block generics from purchasing Daraprim for bioequivalence testing, API exclusivity agreements to deny generic companies' access to the most viable suppliers of a key ingredient, and data-blocking agreements to shroud the Daraprim market opportunity and deter generic entry—independently states a claim for monopolization under the rule of reason. But these various types of agreements also work synergistically as an overall scheme to impede and delay generic entry at every point. Thus, as Vyera acknowledges, the complaint must be read "without tightly compartmentalizing the[se] various factual components and wiping the slate clean after scrutiny of each." Mem. 37 (quoting *Cont'l Ore Co. v. Union Carbide & Carbon Corp.*, 370 U.S. 690, 699 (1962)); *see also Namenda II*, 787 F.3d at 653-54.

IV. The complaint states valid claims of unreasonable restraints of trade

Plaintiffs also plausibly allege that Vyera's resale-restriction agreements and exclusive API contracts are, independently, unreasonable restraints of trade. The elements of this claim are (1) an agreement between two distinct participants that (2) "constitute[s] an unreasonable restraint of trade either per se or under the rule of reason." *Primetime 24 Joint Venture v. Nat'l Broadcasting Co.*, 219 F.3d 92, 103 (2d Cir. 2000) (citation omitted).[37] As described above, the challenged agreements are anticompetitive and thus constitute unreasonable restraints of trade

[37] Establishing an agreement in restraint of trade may also require showing that the parties to the agreement had market power. *Geneva Pharm.*, 386 F.3d at 509. Vyera's motion to dismiss does not contest Plaintiffs' allegations of market power.

under the rule of reason. But Defendants separately argue that Vyera's written contractual restrictions with distributors, purchasers, and API suppliers do not count as "agreement[s] between two distinct participants." *See* Mem. 38-39 (asserting the complaint fails to allege concerted action).[38] This argument can be easily rejected.

A. Defendants' written contracts establish concerted action

"The first crucial question in a Section 1 case is [] whether the challenged conduct stems from independent decision or from an agreement, tacit or express." *United States v. Apple, Inc.*, 791 F.3d 290, 314-15 (2d Cir. 2015) (internal quotation omitted). This question of concerted action is "different from and antecedent to the question whether [that concerted action] unreasonably restrains trade." *Am. Needle, Inc. v. Nat'l Football League*, 560 U.S. 183, 186 (2010). "Only after an agreement is established will a court consider whether the agreement constituted an unreasonable restraint of trade either per se or under the rule of reason." *AD/SAT, Div. of Skylight, Inc. v. Associated Press*, 181 F.3d 216, 232 (2d Cir. 1999).

Where, as here, there is a written agreement to engage in the challenged conduct, this first element is easily satisfied. As the leading antitrust treatise explains, "[a]n agreed restraint upon a dealer's freedom of action is a 'contract . . . in restraint of trade' governed by Sherman Act §1." 6 Philip E. Areeda & Herbert Hovenkamp, Antitrust Law ¶ 1609a (4th ed. 2017); *see also id.* ¶ 1400c ("An undisputed contract remains an agreement for antitrust purposes.").[39] The written

[38] Defendants do not dispute that Vyera and each of its suppliers, purchasers, and distributors constitute separate economic actors capable of entering an agreement that restrains trade. Nor could they, given that each is plainly an "independent center[] of decisionmaking" that is independently owned, independently managed, and separately controlled." *Am. Needle*, 560 U.S. at 195-96. Instead Defendants simply argue that there is insufficient evidence of agreements between the parties. Mem. 38-39.

[39] To be sure, it is not enough to simply point to a written contract involving the defendant if that contract does not evidence the agreement being challenged. For example, the plaintiff in *Merced Irrigation Dist. v. Barclays Bank PLC*, 165 F. Supp. 3d 122 (S.D.N.Y. 2016), alleged that a monopolist's financial market transactions with unidentified counterparties had an aggregate anticompetitive effect. But the plaintiff did not challenge any provisions within the individual contracts or allege that the contracts themselves "by [their] terms, created an anti-
(Continued…)

contracts in this case conclusively establish that the distributors', purchasers', and API suppliers' refusal to sell to generic companies stems "from an agreement," not from "independent decision." *Apple*, 791 F.3d at 314-15.

This principle is well established in the Second Circuit. In *E & L Consulting*, the Second Circuit found that an exclusive distribution agreement, "like any commercial agreement, restrains trade" and thus establishes concerted action. 472 F.3d at 29, 31-33 (dismissing at the next step of the analysis because "nothing in the complaint suggests that this agreement results" in an unreasonable restraint). In *Geneva Pharmaceuticals*, the Second Circuit observed that "the exclusive dealing arrangement itself satisfies the § 1 requirement of coordinated action." 386 F.3d at 507-08.[40] And other recent decisions from this district have similarly found vertical written agreements "sufficient to establish concerted action." *Namenda I*, 2014 WL 7015198, at *41 (pharmaceutical distribution agreement satisfied concerted action element).[41]

Applying these well-settled principles here, Vyera's written contracts with its distributors, purchasers, and API suppliers establish concerted action. The complaint does not just allege "the mere existence of a contract" with those parties (Mem. 38); it alleges that they expressly agreed to restrict their commercial behavior by not selling key inputs to potential

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competitive effect." *Id.* at 139. The court thus held that the sale transaction contracts on their own did not establish concerted action *Id.* at 139-40.

[40] This conclusion is consistent with over a century of Supreme Court and Second Circuit precedent addressing Section 1 liability in cases with explicit vertical restraints without further analysis of concerted action. *See supra* pgs. 34-37.

[41] *See also Keurig*, 383 F. Supp. 3d 187, 245-46 (S.D.N.Y. 2019) (allegations that Keurig "secured a network of agreements from licenses" not to deal with Keurig's competitors sufficiently alleged "a vertical group boycott that would violate Section 1"); *Wellnx*, 516 F. Supp. 2d at 290-91 (finding cognizable Section 1 agreements between a manufacturer of bodybuilding supplements and publishers of bodybuilding periodicals where one of the agreements was established through an "explicit" written contract allowing the manufacturer to restrict the publisher's choice of advertisers).

generic competitors. Am. Compl. ¶¶ 100-22, 123-28, 134-37. In other words, they expressly agreed to engage in the conduct challenged in the complaint.

B. Direct evidence of an agreement obviates the need to allege a "unity of purpose"

Defendants erroneously insist that, in addition to a written agreement not to sell to generic companies, the complaint must also allege a "unity of purpose, or a common design and understanding, or a meeting of minds." Mem. 38 (quoting *In re Elec. Books Antitrust Litig.*, 859 F. Supp. 2d 671, 681 (S.D.N.Y. 2012)). But this type of additional proof is only required when an agreement is alleged but there is no direct evidence of one. As another court in this district explained, when the "question is whether [the challenged conduct] is the product of coordinated or unilateral decision making, a plaintiff must allege additional facts that point toward a meeting of the minds." *In re Zinc Antitrust Litig.*, 155 F. Supp. 3d 337, 366 (S.D.N.Y. 2016). But when (as here) a challenged restraint is memorialized in a written agreement, "[t]here is no need to show a common purpose in order to prove the absence of independent action because the . . . contract amply demonstrates that there was no independence of action." *Eskofot A/S v. E.I. Du Pont de Nemours & Co.*, 872 F. Supp. 81, 92 (S.D.N.Y. 1995); *see also In re Androgel Antitrust Litig. (No. II)*, 1:09-MD-2084-TWT, 1:09-CV-955-TWT, 2018 WL 2984873, at *7-8 (N.D. Ga. June 14, 2018) ("agreements that specifically address the conduct the Plaintiffs argue is unlawful" establish concerted action).[42]

Thus, for example, the fact that two competitors charge the same price would be insufficient by itself to establish a price-fixing agreement, and a complaint would need to present

[42] None of the cases cited by Defendants involved an express written agreement to engage in the challenged conduct. In both *Anderson News,* 680 F.3d at 186-89, and *International Distribution Centers, Inc. v. Walsh Trucking Co.*, 812 F.2d 786, 793-94 (2d Cir. 1987), there were allegations of parallel conduct but no express agreement. In *In re Electronic Books Antitrust Litigation*, although there were express vertical agency agreements between Apple and the publisher defendants, the "agreement described in the complaint" was an unwritten "horizontal agreement among the publishers." 859 F. Supp. 2d 671, 691-92 (S.D.N.Y. 2012) (Cote, J.).

additional "circumstantial facts supporting the *inference* that a conspiracy existed." *See Mayor & City Council of Baltimore v. Citigroup, Inc.*, 709 F.3d 129, 136 (2d Cir. 2013). But a written agreement between two competitors to fix prices requires no further evidence of concerted action. *Id*. ("Allegations of direct evidence of an agreement, if sufficiently detailed, are independently adequate." (internal quotation omitted)). The written contracts in this case likewise provide direct evidence of an agreement not to sell to generic companies and require no circumstantial facts to establish concerted action.

Nor are Plaintiffs required to allege that Vyera's distributors, purchasers, or suppliers had an "independent desire or incentive to harm prospective generic competitors." Mem. 39. As the leading treatise explains, the "quid" that a supplier or distributor receives in a Section 1 case "may be thought peculiar . . . namely that a customer merely continues to purchase or a supplier merely continues to supply." Areeda ¶ 1402b4. "But this peculiarity presents no obstacle to treating the restraining promise as a conspiracy." *Id.*; *see also Apple*, 791 F.3d at 317 ("Antitrust law has never required identical *motives* among conspirators when their independent reasons for joining together lead to collusive action." (internal quotation omitted)); *Paladin Assocs., Inc. v. Montana Power Co.*, 328 F.3d 1145, 1153-54 (9th Cir. 2003) (plaintiff "need not prove intent to control prices or destroy competition to demonstrate the element of an agreement among two or more entities" (internal quotation omitted)).[43]

Indeed, in a case involving written vertical contracts (like those alleged here), a Section 1 agreement exists even where the purchaser or distributor opposes the manufacturer's

[43] The term "conspiracy" does not carry the same nefarious connotations in antitrust law as in other areas of the law. "Outside the antitrust context, the term 'conspiracy' is restricted to agreements with unlawful objectives or means. In the antitrust universe, the existence of an agreement must always be considered separately from the question of legality." Areeda ¶ 1400b; *see also Am. Needle*, 560 U.S. at 186. Thus, an antitrust "conspiracy" arises whenever two parties jointly agree to something that restrains trade—whether or not that restraint of trade is illegal.

anticompetitive purpose: "Unlike the standard cartel among equally 'sovereign' sellers, the vertical agreement often involves a dependent party. The manufacturer or the dealer might be imposing its will on the other. Nonetheless, the collaboration between those parties creates the restraint." Areeda ¶ 1402b4; *see also id.* ¶ 1408d ("[T]he legal convention of treating express promises in the vertical context as §1 contracts or conspiracies is well established, notwithstanding an unwilling dealer.").[44]

The recent *American Express* antitrust litigation illustrates this well-established principle. In that case, Amex required its merchants "to agree to an antisteering contractual provision" that prohibited them from encouraging customers from using an alternative credit card to make a purchase. 138 S. Ct. at 2280. Even though the anti-steering restriction was imposed by Amex, and contrary to the merchants' self-interest, the district court found the written contract "satisf[ied] the concerted action element of a Section 1 violation." *United States v. American Express Co.*, 88 F. Supp. 3d 143, 167 (E.D.N.Y. 2015) (internal quotation omitted). The Second Circuit and Supreme Court, although reversing on other grounds, agreed that the provisions were "vertical restraints—*i.e.*, restraints imposed by agreement between firms at different levels of distribution"—and subject to the antitrust rule of reason analysis. *American Express*, 138 S. Ct. at 2284 (internal quotation omitted); *United States v. American Express Co.*, 838 F.3d 179, 195-96 (2d Cir. 2016).

Defendants' "unity of purpose" argument rests almost entirely on a single out-of-circuit district court case, *Mylan Pharmaceuticals v. Celgene Corp.*, involving a brand company's efforts to prevent potential generic competitors from obtaining samples of its products for

[44] Another example is a Section 1 tying case. A plaintiff that was forced to purchase the tied products can "show that it entered into a contract or combination with defendant" by proving "that it agreed to the alleged tying arrangement." *R & G Affiliates, Inc. v. Knoll Int'l, Inc.*, 587 F. Supp. 1395, 1398-99 (S.D.N.Y. 1984).

bioequivalence testing. Civil No. 14-2094 ES, 2014 WL 12810322 (D.N.J. Dec. 23, 2014). In that case, although the court allowed Mylan's monopolization claim to proceed (*id.* at *3-6), it dismissed Mylan's Section 1 claims because Mylan had not pled that "Celgene's distributors and pharmacists shared its purpose" or "even had knowledge of Celgene's anticompetitive intent." *Id.* at *8 (alterations omitted).

To the extent that *Mylan* required the plaintiff to show more than an express written agreement to engage in the challenged conduct, it is inconsistent with the numerous decisions discussed above. But even under this erroneous standard, Plaintiffs' allegations are more than sufficient. The complaint plausibly alleges that (1) the distributors and purchasers were aware of Defendants' anticompetitive purpose, which was publicly reported in the New York Times and publicized by a Senate investigation and report (Am. Compl. ¶¶ 137-40); (2) Vyera directly told at least one distributor that its resale limits were designed to prevent a generic company from "access[ing] multiple bottles" of Daraprim (*id.* ¶ 125); (3) most of the distributors financially benefitted from the continued monopoly price of Daraprim because they were [redacted] (*id.* ¶¶ 105, 107, 109); (4) Vyera expressly told Fukuzyu that it wanted an exclusive API agreement to block generic competitors and implied that Fukuzyu's compliance would result in future business collaborations (*id.* ¶ 155); and (5) RL Fine received [redacted] in return for agreeing to exclusivity and discontinuing its relationship with two generic companies (*id.* ¶¶ 165-66). In sum, Plaintiffs' complaint amply alleges that Vyera's distributors and suppliers "had knowledge of" and "stood to benefit from" the anticompetitive agreements. *Mylan*, 2014 WL 12810322, at *8.

CONCLUSION

For the foregoing reasons, Plaintiffs respectfully submit that the Court should deny Vyera's motion to dismiss in full.

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CERTIFICATE OF SERVICE

I hereby certify that on July 6, 2020, I have electronically filed a true and correct copy of the **Plaintiffs' Memorandum of Law in Opposition to Defendants Vyera Pharmaceuticals, LLC and Phoneixus AG's Motion to Dismiss** with the Clerk of the Court using the CM/ECF system, which will automatically send e-mail notification of such filing to all counsel of record.

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